REMARKS

Receipt of the Office Action, mailed January 15, 2004, is acknowledged. Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow. This amendment changes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

Claims 7, 8, 16, 25, 30, and 42 are currently being amended. No claims are being added or cancelled. After amending the claims as set forth above, claims 1-8, 10, 11, 13-16, 18, 19, 21-30, 32, 33, 35-42, 44, 45, and 47-55 are now pending in this application. Claims 1-6 and 50-55 are withdrawn from further consideration. Claims 7, 8, 10, 11, 13-16, 18, 19, 21-30, 32, 33, 35-42, 44, 45, and 47-49 are now under consideration.

There are three rejections of record. First, claims 7, 8, 10, 11, 15, 16, 18, and 19 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Lowrie *et al.* (Vaccine, 15(8):834-838 (1997)). Second, claims 23, 25-30, 32, 33, 37-42, 44, and 45 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Lowrie in view of Sanford *et al.* (United States Patent No. 5,100,792). Finally, claims 8, 10, 11, 13, 14, 16, 18, 19, 21-39, 32, 33, 35-42, 44, 45, and 47-49 stand rejected under 35 U.S.C. § 112, ¶ 2, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants note with appreciation that the Examiner has withdrawn the following objections and rejections to the claims: (a) the objection to claim 26; (b) the rejection of claim 8, 16, 30, and 42, under 35 U.S.C. § 112, ¶ 2, for indefiniteness; (c) the rejection of claims 7, 8, 10, 11, 13-16, 18, 19, 21-30, 32, 33, 35-42, 44, 45, and 47-49 under 35 U.S.C. § 112, ¶ 1, for lack of enablement; and (d) the rejection of claims 8, 10, 11, 13, 16, 18, 19, 21, 30, 32, 33, 35, 42, 44, 45, and 47 also under 35 U.S.C. § 112, ¶ 1, for lack of enablement.

I. 35 U.S.C. § 103(a): The Claims are Patentable Over Lowrie *et al.*

The Examiner has rejected claims 7, 8, 10, 11, 15, 16, 18, and 19 as obvious over Lowrie *et al.* Specifically, the Examiner directs applicants' attention to page 837, col. 2, ll. 11-15 of Lowrie, which states that "a vaccine that gives protection equal to BCG by endogenous expression of only a few proteins will leave the majority of the species specific antigens available for diagnostic tests in vaccinated populations." The Examiner concludes, based on this statement, that Lowrie teaches "a vaccine composition which contains a 'plurality' of antigens, i.e., 'only a few proteins.'" Applicants submit that the statement in Lowrie is, at best, unclear. In addition, applicants submit that Lowrie does not teach or suggest the claimed invention.

The claimed invention relates to a vector construct that comprises a polynucleotide. The recited polynucleotide in turn comprises a "plurality of antigens." The polynucleotide identified in the claim is unlike the nucleotide sequences disclosed in Lowrie, which only contain a single antigen.

Even if one were to assume that the Examiner's assertion is correct that Lowrie teaches "a vaccine composition which contains a 'plurality' of antigens," Lowrie still does not teach or suggest a polynucleotide comprising a plurality of antigens. Instead, it teaches a vaccine that expresses a plurality of proteins , where the proteins each contain a single antigen. It does not teach that each protein comprises a plurality of antigens. Accordingly, Lowrie does not teach or suggest a vaccine that contains a vector, where each vector contains a recombinant polynucleotide that has a plurality of *Mycobacterium tuberculosis* antigens as claimed in the present application. The claimed invention would not have been obvious over Lowrie since the recited methods employ a polynucleotide that includes a plurality of antigens and Lowrie does not disclose this claim element.

Applicants, by amending claim 7, are attempting to make this distinction clear in order to move the claims to allowance. Applicants do not intend to abandon claimed subject matter by this amendment or acquiesce in the rejection; rather, they submit that the scope of the claim has not been changed.

Finally, Lowrie provide no motivation to modify the disclosed vaccines to arrive at the claimed invention. Lowrie indicates that three of the single antigen DNA vaccines tested "elicited significant protection." Page 837, col. 1, 3rd full paragraph. Lowrie also suggests that "[f]urther comparisons in outbred mice ... will be needed before conclusions can be drawn as to which antigens are the best candidates for inclusion in a practical vaccine." Page 837, col. 1&2, final paragraph. Finally, Lowrie states that the studies it conducted "indicate that vaccines that are superior to BCG may not be far away." Based on these statements, one of skill in the art would be motivated to run similar experiments to those disclosed with other antigens to find additional vaccines that elicit significant protection or to find vaccines that are superior to BCG. Lowrie, however, provides no motivation to one skilled in the art to modify the single antigen DNA disclosed to arrive at the polynucleotide comprising a plurality of antigens that is claimed.

II. 35 U.S.C. § 103(a): The Claims are Patentable Over Lowrie *et al.* in view of Sanford *et al.*

The Examiner also rejected claims 23, 25-30, 32, 33, 37-42, 44, and 45 as being obvious over Lowrie in view of Sanford. Without acquiescing in the rejection and without intending to abandon claimed subject matter but to expedite allowance, claim 25 has been amended to clarify the claim language in the same manner as claim 7 above. As stated, the primary reference Lowrie fails to teach the recited multiple antigen polynucleotide. Sanford does not provide the missing teaching or suggestion. Therefore, these claims are patentable over the combination of Lowrie and Sanford.

III. 35 U.S.C. § 112, ¶ 2: The Claims are Definite and Clear

The Examiner further rejected claims 8, 10, 11, 13, 14, 16, 18, 19, 21-39, 32, 33, 35-42, 44, 45, and 47-49 as indefinite. Specifically, the Examiner found the phrase "said plurality of *M. Tuberculosis* antigens in peptide or protein form" unclear. Without acquiescing in the rejection and without intending to abandon claimed subject matter but to expedite allowance, claims 8, 16, 30, and 42 have been amended to remove the objectionable claim language, "in peptide or protein form." Applicants submit that it is well known that antigens exist in protein and peptide form and therefore the claims have not been narrowed by

this amendment. In addition, claims 10, 11, 13, 14, 18, 19, 21-29, 32, 33, 35-41, 44, 45, and 47-49 depend from these claims, which are clear and definite.

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, applicants hereby petition for such extension under 37 C.F.R. § 1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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By Richard C. Peet

FOLEY & LARDNER LLP
Customer Number 27476
Telephone: (202) 672-5483
Facsimile: (202) 672-5399

Richard C. Peet
Attorney for Applicant
Registration No. 35,792